

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the **Federal Register—Environmental Documents**." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

To access a fact sheet which provides more detail on this registration, go to the Home Page for the Office of Pesticide Programs at <http://www.epa.gov/pesticides/>, and select "fact sheet."

2. *In person.* The Agency has established an official record for this action under docket control number OPP-30475A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well

as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm.119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are also available for public inspection. Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 1200 Pennsylvania Ave., NW., Washington, DC 20460. The request should: Identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet, which provides more detail on this registration, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

II. Did EPA Approve the Application?

The Agency approved the application after considering all required data on risks associated with the proposed use of 4-allyl anisole, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of 4-allyl anisole when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

III. Approved Application

EPA issued a notice, published in the **Federal Register** of April 20, 1999 (64 FR 19356) (FRL-6072-9), which announced that Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430, had submitted an application to register the pesticide product, Beetleball Technical, a technical

product to be used to manufacture invertebrate repellents (EPA File Symbol 72098-U), containing 97.5% 4-allyl anisole. This product was not previously registered.

The application was approved on September 28, 2001, as Beetleball Technical (EPA Registration Number 72098-4) for use in manufacturing invertebrate repellents.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: October 31, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

FR Doc. 01-28741 Filed 11-20-01; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1056; FRL-6811-7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-1056, must be received on or before December 21, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1056 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

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Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1056 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-1056. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be

disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record.

Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: November 8, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569, the registrant, and represents the view of Gowan Company. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4

0E6165

EPA has received a pesticide petition (0E6165) from the Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.145 by establishing a tolerance for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) in or on the raw agricultural commodities peppermint tops and spearmint tops at 50 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition. This notice of filing contains a summary of the petition provided by Gowan Company, the registrant.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residue in plants is understood, and that plant residues are inorganic surface residues of cryolite which are measured as fluoride.

2. *Analytical method.* Adequate methodology is available for data collection and tolerance enforcement. Methods for plant residues have undergone successful Agency validation and will be published in Pesticide Analytical Manual (PAM), Vol. II. Using

these methods, total fluoride is determined using a pH/ion meter with a fluoride-specific electrode. The residue analytical method does not distinguish between naturally occurring fluoride and fluoride resulting from agricultural use of cryolite. Current Food and Drug Administration (FDA) multi-residue screening protocols are not appropriate for inorganic fluoride residues.

3. *Magnitude of residues.* A tolerance of 50 ppm is supported for fluoride in or on mint tops for the use pattern of 36 pounds active ingredient/acre per season of Gowan cryolite bait (20% granular).

B. Toxicological Profile

1. *Acute toxicity.* A rat acute oral toxicity study showed a lethal dose (LD)₅₀ greater than 5,000 milligrams/kilograms (mg/kg). A rabbit acute dermal toxicity study demonstrated an LD₅₀ of 2,100 mg/kg. A lethal concentration (LC)₅₀ >2.06 milligram per liter (mg/L) and <5.03 mg/L was seen in an acute inhalation study with rats. Technical cryolite is a moderate eye irritant in rabbits. Cryolite is not a skin irritant to rabbits and is not a dermal sensitizer to guinea pigs.

2. *Genotoxicity.* Cryolite was negative in an Ames reverse mutation test using *Salmonella typhimurium* with and without activation at dose levels of 167, 500, 1,670, 5,000, 7,500, and 10,000 µg/plate. Cryolite was tested in an *in vitro* chromosome aberration assay using human lymphocytes at 100, 500, and 1,000 µg/mL, with and without activation. The results were negative. Cryolite also was negative in an unscheduled DNA synthesis (UDS) study with rat hepatocytes at dose levels up to and including 50 µg/mL.

3. *Developmental and reproductive toxicity.* A developmental toxicity study was performed with cryolite in rats at dose levels of 0, 750, 1,500, and 3,000 mg/kg/day (gavage). The no observed adverse effect level (NOAEL) for both developmental and maternal toxicity was 3,000 mg/kg/day. At this dose level, the only observation was whitening of the teeth of dams.

A developmental toxicity study was conducted in female mice with cryolite at dose levels of 0, 30, 100, and 300 mg/kg/day (gavage). The NOAEL for maternal toxicity was 30 mg/kg/day and the lowest observed adverse effect level (LOAEL) was 100 mg/kg/day based on a single mortality in this group. Fetuses at 300 mg/kg/day exhibited bent ribs and bent limb bones. The NOAEL for developmental toxicity was 100 mg/kg/day. The LOAEL was 300 mg/kg/day based on an increase in bent ribs and

bent limbs. A range-finding developmental toxicity study in female rabbits tested cryolite at dose levels of 0, 10, 30, 100, 300, and 1,000 mg/kg/day (gavage). The NOAEL for maternal toxicity was determined to be 10 mg/kg/day and the LOAEL was 30 mg/kg/day based on an increased incidence of soft stool and dark colored feces and decreased defecation and urination. The NOAEL for developmental toxicity was 30 mg/kg/day. The developmental LOAEL could not be assessed due to excessive maternal toxicity at dose levels of ≥30 mg/kg/day.

A 2-generation rat reproduction study was conducted with cryolite at dietary dose levels of 0, 200, 600, and 1,800 ppm (representing 0, 14, 42, and 128 mg/kg/day for males and 0, 16, 49, and 149 mg/kg/day for females, respectively, during premating). The systemic toxicity NOAEL was not determined. The LOAEL for systemic toxicity was 200 ppm (15 mg/kg/day) based on dental fluorosis. The NOAEL and LOAEL for reproductive toxicity were 600 and 1,800 ppm, respectively (46 and 138 mg/kg/day) based on decreased pup body weights.

4. *Subchronic toxicity.* Cryolite was tested in a 28-day range-finding feeding study in rats at dose levels of 0, 250, 500, 1,000, 2,000, 4,000, 10,000, 25,000, and 50,000 ppm in the diet (representing approximately 0, 25, 50, 100, 200, 400, 1,000, 2,500, and 5,000 mg/kg/day). The only compound-related effect seen in this study was a change in coloration and physical property of the teeth. A NOAEL was not determined in this study. The LOAEL is 250 ppm (25 mg/kg/day) based on dental fluorosis.

In a 90-day rat feeding study, cryolite was tested at dose levels of 0, 50, 5,000, and 50,000 ppm (corresponding to 0, 3.8, 399.2, and 4,172.3 mg/kg/day in males and 0, 4.5, 455.9, and 4,758.1 mg/kg/day in females). The NOAEL was 50 ppm (3.8 mg/kg/day) for effects other than fluoride accumulation. The LOAEL was 5,000 ppm (399.2 mg/kg/day) based on lesions observed in the stomach. Fluoride accumulated at all dose levels in this study.

Cryolite was tested in a 90-day dog feeding study at dose levels of 0, 500, 10,000, and 50,000 ppm (corresponding to 0, 17, 368, and 1,692 mg/kg/day). The NOAEL was 10,000 ppm (368 mg/kg/day). The LOAEL was 50,000 ppm (1,692 mg/kg/day) for effects other than fluoride accumulation. Fluoride accumulation occurred at all dose levels.

A 21-day subchronic dermal toxicity study in rabbits is considered invalid because it is likely that cryolite was

ingested by the test animals during the study. For this reason, the systemic dermal NOAEL and LOAEL could not be determined from this study.

5. *Chronic toxicity.* A 2-year bioassay in B6C3F1 mice was conducted by the National Toxicology Program (NTP) using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 2.4, 9.6, and 16.7 mg/kg/day in males and 0, 2.8, 11.3, and 18.8 mg/kg/day in females. The NOAEL was less than 25 ppm (2.4 mg/kg/day). The LOAEL was 25 ppm (2.4 mg/kg/day) based on attrition of the teeth in males, discoloration and mottling of the teeth in males and females and increased bone fluoride in both sexes. NTP considered that there was no evidence of carcinogenic activity in male and female mice.

A 2-year bioassay in F344/N rats also was conducted by the NTP using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 1.3, 5.2, and 8.6 mg/kg/day in males and 0, 1.3, 5.5, and 9.5 mg/kg/day in females. Osteosarcoma of the bone was observed only in 1 male of 50 (1/50) in the 100 ppm group and in 3 of 80 (3/80) males in the 175 ppm group. The NOAEL was less than 25 ppm (1.3 mg/kg/day). The LOAEL was 25 ppm (1.3 mg/kg/day) based on mottling of teeth, dentine incisor dysplasia, increased serum, urine, and bone fluoride levels in males and females and incisor odontoblast and incisor ameloblast degeneration in males. NTP considered that there was equivocal evidence of carcinogenic activity in male rats in this study and no evidence of carcinogenic activity in female rats.

A 1-year chronic dog feeding study was conducted with cryolite at dose levels of 0, 3,000, 10,000, and 30,000 ppm, representing 0, 95, 366, and 1,137 mg/kg/day in males and 0, 105, 387, and 1,139 mg/kg/day in females (in terms of fluoride the doses are 0, 51, 198, and 614 mg F/kg/day for males and 0, 57, 209 and 615 mg F/kg/day for females). The NOAEL was less than 3,000 ppm (95 mg/kg/day in males and 105 mg/kg/day in females). The LOAEL was 3,000 ppm based on increases in emesis, nucleated cells in males, renal lesions, and a decrease in urine-specific gravity in females.

6. *Animal metabolism.* Cryolite metabolism in animals manifests itself as free fluoride, that the qualitative nature of the residue is understood and that total fluoride is the residue of concern.

7. *Metabolite toxicology.* Cryolite behaves toxicologically as free fluoride.

That is, dissociation produces free fluoride ions which are assimilated into bone. There are numerous references in the open literature concerning the metabolism of cryolite and other fluoride salts. The National Research Council concluded in their 1993 comprehensive report titled "Health Effects of Ingested Fluoride," that fluoride is readily absorbed by the gut and rapidly becomes associated with teeth and bones. The remaining fluoride is eliminated almost exclusively by the kidneys with the rate of renal clearance related directly to urinary pH.

8. *Endocrine disruption.* The 2-generation rat reproduction study, the rat, rabbit, and mouse developmental studies, and the dog chronic studies summarized above did not demonstrate any effects with cryolite that are similar to those produced by naturally occurring estrogens, or other endocrine effects. No endocrine effects were determined in the rat and mouse (NTP) studies.

C. Aggregate Exposure

1. *Dietary exposure.* For acute dietary exposure, no endpoint of concern could be found from which an acute dietary risk assessment (1 day) should be conducted. There was no endpoint for acute dietary exposure, since acute toxicity in animal studies is absent until very high doses of cryolite were used.

i. *Food.* The Agency has estimated chronic dietary exposure to cryolite using reassessed tolerances for all currently registered crops and percent of crop treated assumptions. The estimated dietary exposure to cryolite from all crops is approximately 0.020 mg/kg/day for the U.S. population, 0.024 mg/kg/day for children 1 to 6 years old, 0.015 mg/kg/day for children 7 to 12 years old, and 0.028 mg/kg/day for nursing females 13+ years. For the highest exposed subgroup (females 20 years old and over), the Agency estimated exposure of 0.038 mg/kg/day.

A Tier 1 chronic dietary risk assessment based on the proposed tolerance of 50 ppm for mint top, the conservative assumption of 1 ppm (limit of detection) in mint oil, and 100 percent crop treated indicates that the additional exposure to fluoride caused by the proposed tolerance would be miniscule. The Tier 1 chronic assessment, performed with Novigen Sciences Inc. Dietary Exposure Evaluation (DEEM) software shows that the highest exposed populations, children 1 to 6 years old and 7 to 12 years old, would be exposed to an additional 0.000001 mg/kg/day. The total U.S. population and all other population subgroups would be exposed

to less 1×10^{-6} mg/kg/day, which is the smallest value. Based on the results of this conservative model, additional exposure caused by the proposed tolerance would be negligible.

ii. *Drinking water.* The Agency concluded that the use of cryolite should have negligible impacts on fluoride levels in ground and surface water. For this reason, the contribution of cryolite to potential exposure to fluoride from drinking water need not be considered in the aggregate risk assessment.

However, fluoride is intentionally supplemented to drinking water for prevention of dental caries and may also be present at natural background levels. The U.S. Public Health Service recommends an optimal fluoride concentration of 0.7–1.2 mg/L to prevent dental caries and minimize dental fluorosis. Fluoride levels in public drinking water are regulated under the Safe Drinking Water Act. A maximum concentration limit (MCL) of 4.0 mg/L (0.114 mg/kg/day) has been established.

EPA has previously estimated that levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies result in a daily dietary intake of fluoride of approximately 0.085 mg/kg/day. This is substantially less than the MCL of 4.0 mg/L (0.144 mg/kg/day), a level which provides no known or anticipated adverse health effect as determined by the Surgeon General.

2. *Non-dietary exposure.* EPA previously concluded on December 5, 1997 (62 FR 64294) (FRL-5756-5), that significant non-dietary (residential) exposure from the use of cryolite is not anticipated.

D. Cumulative Effects

The residue of toxicological concern in cryolite is fluoride. However, current tolerances for insecticidal fluorine-containing compounds are limited to cryolite and synthetic cryolite. For this reason, consideration of potential cumulative effects of residues from pesticidal substances other than sodium aluminofluoride with a common mechanism of toxicity are not applicable.

E. Safety Determination

1. *U.S. population.* As discussed above, non-dietary exposure to cryolite is negligible. For dietary exposure, EPA concluded that rather than establishing a traditional reference dose (RfD), a weight-of-the-evidence risk assessment is a more appropriate approach for cryolite. The toxicological endpoint of

concern for dietary exposure to cryolite is skeletal fluorosis.

EPA estimated that total dietary fluoride exposure, including food and drinking water, is 0.085 mg/kg/day. Of this total exposure, the dietary (food) contribution is about 0.020 mg/kg/day for the U.S. population and 0.028 mg/kg/day for the highest exposed subgroup (nursing females 13 years old and over). The proposed mint tolerances will contribute no more than 0.000001 mg/kg/day to total dietary exposure. Thus, the proposed tolerance would have essentially no effect on total fluoride exposure. The total exposure to fluoride from all sources is well below the MCL of 4.0 mg/L (0.114 mg/kg/day).

2. *Infants and children.* EPA has previously concluded on December 5, 1997 (62 FR 64294), that based on current data requirements, the data base relative to prenatal and postnatal toxicity is complete. This data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased prenatal or postnatal sensitivity. Therefore, EPA concluded that reliable data support the weight-of-evidence risk assessment approach for the assessment of risks to infants and children associated with the use of cryolite and that an additional safety factor is not needed.

F. International Tolerances

No Codex, European or other international tolerances are in effect for cryolite; thus potential dietary exposure to fluoride from the agricultural use of cryolite on crops would not include imported foodstuffs.

[FR Doc. 01-28861 Filed 11-20-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1042; FRL-6799-1]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-1042, must be received on or before December 21, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

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FOR FURTHER INFORMATION CONTACT: By mail: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8391; e-mail address: kumar.rita@epa.gov.

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